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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,355	03/01/2002	Richard C. Boucher JR.	5470.250DV	3423

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,355

Applicant(s)

BOUCHER, RICHARD C.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14,15,20,31-44 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,15,20,31-44 and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1617

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2003 has been entered.

Applicants' election in the parent application is presumed to carry over to the instant RCE since applicants have not indicated a contrary intention.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14, 15, 20, 31-44 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (U.S. Patent 5,863,563, of record) in view of Cropp and Glass (U.S. Patent 5,162,348, of record).

3. Scheele teaches a method for treating symptom of a patient who has pulmonary conditions, including cystic fibrosis, the method comprising causing the patient inhale a composition comprising alkali metal salts, such as potassium salt or sodium salts. Various anions may be employed, including bicarbonate. See, column 5, line 52 bridging column 6, line 18, and the claims.

Art Unit: 1617

4. Scheele does not teach expressly the employment of combination of salts, or the further employment of bronchodilator in the composition.

5. However, Cropp and Glass teach that bronchodilators are well known to be useful for treating cystic fibrosis, particularly administered in aerosolized forms. See, particularly, the abstract in Cropp and column 1, lines 44-51 in Glass. Glass further suggests that bronchodilators may be employed with other agents useful for treating cystic fibrosis.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with bronchodilator before administering the instant composition.

A person of ordinary skill in the art would have been motivated to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with bronchodilator before administering the instant composition because all the salts disclosed by Scheele are known to be similarly useful in treating cystic fibrosis and it is *prima facie* obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. The combining treatment with bronchodilator is also obvious since bronchodilator is known to be useful for treating cystic fibrosis. The optimization of a result effective parameter, e.g., the method of administering two agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Art Unit: 1617

Response to the Arguments

Applicants' amendments and remarks submitted November 21, 2003 have been fully considered, but are not persuasive with respect to the rejections under 35 U.S.C. 103 as set forth above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion or motivation is both in the references and in the knowledge generally available to one of ordinary skill in the art. Particularly, As stated above, it is generally considered prima facie obvious to combine two or more compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-cystic fibrosis agents with conventional carriers and excipients. It would follow that the recited claims define prima facie obvious subject matter. Cf. *In re Kerhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Applicants' remarks regarding Scheele reference are not persuasive. First, note every patent is presumed valid (35 U.S.C. 282), and that presumption includes the presumption of operability (*Metropolitan Eng. Co. v. Coe*, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935) (MPEP

Art Unit: 1617

716.06). Second, Scheele teaches a method of treating the symptoms of disorders, including cystic fibrosis, by inhaling potassium salts. A mechanism as why the method is effective is moot with respect to the fact that the method is a known method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


SHENGJUN WANG
Shengjun Wang
PRIMARY EXAMINER

February 16, 2004